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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/214,251 03/10/99 KING

D CARP-0067

EXAMINER

HM12/0321

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HELMS, L  
ART UNIT

PAPER NUMBER

1642  
DATE MAILED:

03/21/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
**09/214,251**

Applicant(s)  
**King et al**

Examiner  
**Larry R. Helms Ph.D.**

Group Art Unit  
**1642**



☒ Responsive to communication(s) filed on 25 Jan 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1, 5, and 9-11 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 5, and 9-11 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

1. Claim 1 has been amended.

Claims 1, 5, and 9-11 are under examination.

2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

### **Rejections withdrawn**

3. Claims 1, 5, 9-10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The rejection of claims 1, and 9-10 and newly added claim 11 under 35 U.S.C. 102(b) as being anticipated by Pedley et al (Br. J. Cancer, Vol. 70, pp 1126-30, 1994) is withdrawn in view of arguments.

5. The rejection of claims 1, 5, and 9-11 under 35 U.S.C. 103(a) as being unpatentable over Pedly et al (Br. J. of Cancer, Vol. 70, pp 1126-30, 1994) and further in view of Goodson et al (Bio/Technology 8:343-346, 1990, IDS # 8) or Woghiren et al (Bioconjugate Chem. 4:314-318, 1993) is withdrawn in view of arguments.

### **Response to Arguments.**

6. The rejection of claims 1 and 9-11 under 35 U.S.C. 102(e) as being anticipated by Griffiths et al (U.S. Patent 5,670,132, filed 9/20/94) is maintained.

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The response filed 1/25/01 has been carefully considered but is deemed not to be persuasive. The response states "Griffiths et al does not disclose each of the elements of the claimed invention" (see page 6 of response) and "Griffiths et al does not provide the degree of the disclosure necessary for one skilled in the art to make the monovalent antibody fragments of the claimed invention" (see page 6 and 7 of response). In response to these arguments, Griffiths et al specifically teaches monovalent antibody fragments (column 3, lines 1-2) and these "fragments" can be PEGylated to a thiol group in the hinge region (column 3, lines 20-24). In addition, it was well known in the art at the time the claimed invention was made under what conditions were critical for reducing disulfide bonds in an antibody. Thus, the art of Griffiths et al reads on the claims.

7. Claims 1, 5, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al (U. S. Patent 5,670,132) and further in view of Goodson et al (Bio/Technology 8:343-346, 1990, IDS # 8) or Woghiren et al (Bioconjugate Chem. 4:314-318, 1993) is maintained.

The response filed 1/25/01 has been carefully considered but is deemed not to be persuasive. The response states Woghiren et al actually teaches away from the use of PEG to modify proteins (see page 10 of response). In response to this argument, the reference cited at the introduction was directed to PEG conjugates with lysine residues. Further disclosed in the introduction is a discussion of PEG conjugation with cysteine residues which "in the reduced

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form is typically less abundant than lysine in the protein" (see introduction). Thus, the teachings of Woghiren et al clearly has motivation to attach PEG to cysteine residues. Therefore, it would have been obvious to covalently attach PEG to cysteine residues in an antibody.

### *Conclusions*

8. No claims are allowed.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with

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alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

  
SHEELA HUFF  
PRIMARY EXAMINER